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657 IAC Chapter 37, Iowa Prescription Monitoring Program Rules

657—37.1(124) Purpose. These rules establish a prescription monitoring program in Iowa that compiles a central database of reportable ~~controlled substances~~ prescriptions dispensed to patients in Iowa. An authorized health care practitioner may, but is not required to, access PMP information regarding the practitioner's patient to assist the practitioner in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a health care practitioner with a resource regarding a patient's use of controlled substances. ~~to~~ This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of those substances without impeding the appropriate medical use of controlled substances.

657—37.2(124) Definitions. As used in this chapter:

"Board" means the Iowa board of pharmacy.

"Controlled substance" means a drug, substance, or immediate precursor in schedules I through V of division II of Iowa Code chapter 124.

"Council" means the advisory council established pursuant to Iowa Code section 124.555 to provide oversight and to comanage PMP activities with the board.

"Database information" or "PMP information" means information submitted to and maintained by the prescription monitoring program database.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration, authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispenser" means a person who delivers to the ultimate user a substance required to be reported to the controlled substance central database~~, but does not include~~ except as follows:

a. A licensed hospital pharmacy ~~that distributes~~ shall not be required to report the distribution of such a substance for the purposes of inpatient hospital care, the dispensing of prescriptions for a starter supply of such a substance at the time of discharge from such a facility, or the dispensing of prescriptions for such a substance in a quantity adequate to treat the patient for a maximum of 72 hours.

b. A licensed pharmacy ~~that distributes~~ shall not be required to report the distribution of such a substance for a patient residing in a long-term care facility or a patient residing in an inpatient hospice facility.

c. A prescriber or other authorized person who administers or dispenses such a substance, including samples of such a substance, for the purposes of outpatient care shall not be required to report such administration or dispensing. This exception shall not apply to a pharmacist who administers such a substance, as directed by the prescriber, pursuant to a prescription.

d. A wholesale distributor of such a substance shall not be required to report the wholesale distribution of such a substance.

ñNDC numberò or ñnational drug codeòmeans the universal product identifier used in the United States to identify a specific human drug product.

ñPatientòmeans the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

ñPatientôs agentòmeans a ~~parent of a minor child, or a~~ person ~~who has been~~ legally authorized to make health care decisions or gain access to health care records on behalf of the patient for purposes of directing the patientôs care.

ñPatients rights committeeò or ñcommitteeòmeans the physician and pharmacist members of the council responsible for monitoring and ensuring protection and preservation of patientsôrights as provided in Iowa Code section 124.555(3)(e).

ñPMP administratoròmeans the board staff person or persons designated to manage the PMP under the direction and oversight of the board and the council.

ñPractitioneròmeans a prescriber or a pharmacist.

ñPrescriberòmeans a licensed health care professional with the authority to prescribe prescription drugs including controlled substances.

ñPrescription monitoring programòor ñPMPòmeans the program established pursuant to these rules for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals, including to health care providers, for use in treatment of their patients.

ñPrescription monitoring program databaseòmeans a centralized database of reportable controlled substances prescriptions dispensed to patients and includes data access logs, security tracking information, and records of each individual who requests PMP information.

ñReportable prescriptionòmeans the record of a schedule II, III, or IV controlled substance dispensed by a pharmacy to a patient pursuant to a prescriber-authorized prescription except as excluded in the definition of ñdispenser.ò

ñSchedule II, III, and IV controlled substancesòmeans controlled substances that are listed in Schedules II, III, and IV of the schedules provided under Iowa Code sections

124.205 through 124.210 or the federal Controlled Substances Act (21 U.S.C. 812).

657—37.3(124) Requirements for PMP. Each dispenser, unless identified as exempt from reporting pursuant to these rules, shall submit to the PMP administrator ~~information regarding each prescription dispensed for a drug included in the PMP~~ a record of each reportable prescription dispensed during a reporting period.

37.3(1) Data elements. The information submitted for each prescription shall include, at a minimum, the following items:

a. Dispenser DEA number,

b. Date the prescription is filled,

c. Prescription number,

d. Indication whether the prescription is new or a refill,

e. NDC number for the drug dispensed,

f. Quantity of the drug dispensed,

g. Number of days of drug therapy provided by this drug as dispensed,

h. Patient name,

i. Patient address including street address, city, state, and zip code,

j. Patient date of birth,

k. Patient gender,

l. Prescriber DEA number,

m. Date the prescription was issued by the prescriber,

n. Method of payment as either third-party payer or patient cash payment.

37.3(2) Reporting periods. A record of each reportable prescription dispensed shall be submitted by each dispenser pursuant to the following schedule. Records may be submitted with greater frequency than required by this schedule. This schedule defines minimum report frequency.

a. Records of reportable prescriptions dispensed between the first and the 15th days of a month shall be submitted no later than the 25th day of the month.

b. Records of reportable prescriptions dispensed between the 16th and the last day of a month shall be submitted no later than the 10th day of the following month.

37.3(~~2~~3). Transmission methods. Transmission of prescription information shall be pursuant to one of the following methods:

a. Data upload to a secure website via Internet connection. The PMP administrator will provide required dispensers with initial secure login and password information. Dispensers will be required to register on the reporting website prior to initial data upload.

b. Electronic media including CD-ROM, DVD, or diskette, accompanied by a

transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media.

c. If a dispenser does not have an automated recordkeeping system capable of producing an electronic report as provided in this rule, the dispenser may submit prescription information on the industry standard universal claim form. The dispenser may complete and submit the claim form on the reporting website or, if the dispenser does not have Internet access, the completed paper claim form may be submitted.

d. Chain pharmacies and pharmacies under shared ownership may submit combined data transmissions on behalf of all facilities by utilizing the secure FTP procedure.

37.3(~~3~~4). Zero reports. If a dispenser has not been identified as exempt from reporting to the PMP and the dispenser did not dispense any reportable prescriptions during a reporting period, the dispenser shall submit a zero report via the established reporting website. If such a dispenser does not have access to the Internet, the dispenser shall notify the PMP administrator via mail or facsimile transmission that the dispenser did not dispense any reportable prescriptions during the reporting period. The schedule identified in subrule 37.3(2) shall determine timely submission of zero reports.

657—37.4(124) Access to prescription information. Prescription information submitted to the board for the PMP database shall be privileged and strictly confidential and not subject to public or open records laws. All information contained in the PMP database, including records of requests for PMP information, shall be privileged and strictly confidential and not subject to public or open records laws. The board, the council, and the PMP administrator shall maintain procedures to ensure that the privacy and confidentiality of patients, prescribers, dispensers, practitioners, and patient information collected, recorded, transmitted, and maintained in the PMP database is not disclosed to persons except as provided in this rule.

37.4(1) Prescribers and dispensers. A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care.

a. Prior to being granted access to PMP information, a practitioner shall submit a request for registration and program access. ~~A practitioner with Internet access may register via a secure website established by the board for that purpose. A practitioner without Internet access shall submit a written registration request on a form provided by the PMP administrator.~~ The PMP administrator shall take reasonable steps to verify the identity of a practitioner and to verify a practitioner's credentials prior to providing a

practitioner with a secure login and initial password. Except in an emergency where the patient would be placed in greater jeopardy by limiting PMP information access to the practitioner, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to the practitioner's agent.

b. A practitioner with Internet access may submit a request for PMP information via a secure website established by the board for that purpose. The requested information shall be provided to the requesting practitioner in a format established by the board and shall be delivered via the secure website.

c. A practitioner without Internet access may submit to the PMP administrator a written request for PMP information via mail or facsimile transmission. The written request shall be in a format established by the board and shall be signed by the requesting practitioner. Prior to processing a written request for PMP information, the PMP administrator shall take reasonable steps to verify the request, which may include but may not be limited to a telephone call to the practitioner at a telephone number known to belong to the practitioner's practice location.

d. A practitioner who requests and receives PMP information consistent with the requirements and intent of these rules may provide that information to another practitioner who is involved in the care of the patient who is the subject of the information. Information from the PMP database remains privileged and strictly confidential. ~~Disclosure of the information~~ Such disclosures among practitioners shall be ~~bound by~~ consistent with these rules and federal and state laws regarding the confidentiality of patient information. ~~and the~~ The information shall be used for medical or pharmaceutical care purposes.

37.4(2) Regulatory agencies and boards. Professional licensing boards and regulatory agencies that supervise or regulate a health care practitioner or that provide payment for health care services~~, as~~ shall be able to access information from the PMP database only if required for ~~an~~ a specific investigation~~, with reasonable~~ of a specific individual licensee as supported by an order, subpoena, or other form of legal compulsion issued upon a determination of probable cause.

a. A director ~~or board investigator~~ of a licensing board with jurisdiction over a practitioner who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the director ~~or board investigator and shall contain a statement of facts from which the PMP administrator may make a determination of reasonable cause for the request. A board that has been granted~~

~~authority under Iowa law for the issuance of investigatory subpoenas shall submit, with the written request, an appropriately executed subpoena~~ and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a finding of probable cause.

b. A director ~~or investigator~~ of a regulatory agency with jurisdiction over a practitioner or with jurisdiction over a person receiving health care services pursuant to one or more programs provided by the agency, who seeks access to PMP information for an investigation, shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the director ~~or investigator and shall contain a statement of facts from which the PMP administrator may make a determination of reasonable cause for the request. A regulatory agency that has been granted authority under Iowa law for the issuance of investigatory subpoenas shall submit, with the written request, an appropriately executed subpoena~~ and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a finding of probable cause.

37.4(3) Law enforcement agencies. Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of any state or federal law relating to controlled substances shall be able to access information from the PMP database by order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a finding of probable cause.

~~a.~~ A law enforcement officer shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the requesting officer or the officerôs superior ~~and shall demonstrate that the officer has probable cause to believe that a violation under any state or federal law relating to controlled substances has occurred and that the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation described~~.

~~b. A~~ The request ~~submitted pursuant to this subrule~~ shall be accompanied by an ~~official court~~ order, subpoena, or warrant issued by a court or legal authority that requires a finding of probable cause and shall be processed by the PMP administrator. A report identifying PMP information relating to the specific individual identified by the ~~court~~ order, subpoena, or warrant may be delivered to the law enforcement officer via mail or alternate secure delivery.

37.4(4) Patients. A patient or the patientôs agent may request and receive PMP

information regarding prescriptions reported to have been dispensed to the patient.

a. A patient may submit a signed, written request for records of the patient's prescriptions dispensed during a specified period of time. The request shall identify the patient by name, including any aliases used by the patient, and shall include the patient's date of birth and gender. The request shall also include any address where the patient resided during the time period of the request and the patient's current address and day time telephone number. A patient may personally deliver the request to the PMP administrator or authorized staff member at the offices of the board located at 400 S.W. Eighth Street, Suite E, Des Moines, IA 50309-4688. The patient will be required to present a current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification shall be maintained in the records of the PMP.

b. A patient who is unable to personally deliver the request to the board offices may submit a request via mail or commercial delivery service. The request shall comply with all provisions of paragraph "a" above, and the signature of the requesting patient shall be witnessed and the patient's identity shall be attested to by a currently registered notary public. In addition to the notary's signature and assurance of the patient's identity, the notary shall certify a copy of the patient's government-issued photo identification and that certified copy shall be submitted with the written request. The request shall be submitted to the Iowa Board of Pharmacy at the address identified in paragraph "a."

c. In the case of a minor child and so long as other provisions of law do not preclude it, the parent or legal guardian may submit a request on behalf of the patient pursuant to the appropriate procedure in paragraph "a" or "b." In addition to the patient's information, the parent or legal guardian shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the parent or legal guardian shall sign the request, certifying that the parent or legal guardian is the legal custodian of the minor child, and the government-issued photo identification shall identify the parent or legal guardian.

d. In the case of a patient whose health care decisions have been legally transferred to a patient's agent, the patient's agent may submit a request on behalf of the patient pursuant to the appropriate procedure in paragraph "a" or "b." In addition to the patient's information, the patient's agent shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the patient's agent shall sign the request and the government-issued photo identification shall identify the patient's agent. The patient's agent shall include a certified copy of the legal document that transferred control over decisions regarding the patient's health care to the patient's agent.

37.4(5) Court orders and subpoenas. The PMP administrator ~~may~~ shall provide PMP information in response to court orders and grand jury subpoenas.

37.4(6) Statistical data. The PMP administrator, following review and approval by the patients rights committee, may provide summary, statistical, or aggregate data to public or private entities for statistical, research, or educational purposes. Prior to the release of any such data, the PMP administrator shall remove any information that could be used to identify an individual patient, prescriber, dispenser, practitioner, or other person who is the subject of the PMP information or data.

37.4(7) PMP administrator access. Other than technical, error, and administrative function reports needed by PMP support staff to determine that records are received and maintained in good order, any other reports concerning the information received from dispensers shall only be prepared at the direction of the board, the council, or the PMP administrator. The board and the council may compile statistical reports from PMP information for use in determining the advisability of continuing the PMP and for use in preparing required reports to the Governor and the legislature. The reports shall not include information that would identify any patient, prescriber, dispenser, practitioner, or other person who is the subject of the PMP information or data.

657--37.5(124) Fees. The board may charge a fee and recover costs incurred for the provision of PMP information, including statistical data, except that no fees or costs shall be assessed to a dispenser for reporting to the PMP or to a practitioner for querying the PMP regarding a practitioner's patient. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

657—37.6(124) PMP information retained. All dispenser records of prescriptions reported to the PMP shall be maintained for a period of four years following the date of the record. All records of access to or query of PMP information shall be maintained for a period of four years following the date of the record. At least semi-annually, all PMP information identified as exceeding that four-year period shall be deleted from the PMP and discarded in a manner to maintain the confidentiality of the PMP information and data. Statistical data and reports that have been cleansed of all personally identifiable information as provided in subrule 37.4(6) or 37.4(7) may be maintained for historical purposes.

657—37.7(124) Information errors. Any person who identifies any PMP information regarding the person that the person believes to be false or in error shall submit a written statement to the PMP administrator. The statement shall identify the information the person believes to be false or in error and the reason the individual believes the

information to be false or in error. The PMP administrator may examine the information identified in the statement and may request the assistance of the boardôs compliance staff to determine whether or not the PMP information is accurate. Prior to initiating any action to correct, delete, or amend any PMP information, the PMP administrator shall submit the statement and the resulting report to the patients rights committee for review and approval of the recommended action. If correction, deletion, or amendment of any PMP information is authorized, that action shall be accomplished within 72 hours of the committeeôs decision. The PMP administrator shall respond, in writing, to the person who submitted the statement charging that the PMP information was false or in error, identifying the action approved by the committee.

657—37.8(124) Dispenser and practitioner records. Nothing in these rules shall apply to records created or maintained in the regular course of business of a pharmacy or health care practitioner and all information, documents, or records otherwise available from those original sources are not to be construed as immune from discovery or use in any civil proceedings merely because the information contained in those records was reported to the PMP in accordance with these rules.

657—37.9(124) Prohibited acts. The PMP administrator shall report to a dispenserôs or a practitionerôs professional licensing board any known violation of the confidentiality provisions or the reporting requirements of these rules for which the dispenser or practitioner is subject to disciplinary action.

37.9(1) Confidentiality. A pharmacy or a practitioner who knowingly fails to comply with the confidentiality provisions of the law or these rules or who delegates PMP information access to another individual, except in an emergency situation as provided in paragraph 37.4(1)(a), is subject to disciplinary action by the appropriate professional licensing board.

37.9(2) Dispenser reporting. A dispenser or a pharmacist that fails to comply with the reporting requirements of the law or these rules may be subject to disciplinary action by the board.